NIAMS Contracts Management Branch

Return to Main Page

Electronic Request for Proposals Number **NIH-NIAMS-03-03**

CLINICAL TRIALS RESOURCE CENTER FOR RHEUMATIC DISEASES

Offerors are responsible for routinely checking this website for any possible solicitation amendments that may be issued. No additional notification of any amendments will be provided.

---

1. *SOLICITATION/CONTRACT FORM COVER PAGE* (SECTION A)

2. *BACKGROUND/STATEMENT OF WORK (with applicable EXHIBITS)*

3. *REPORTING REQUIREMENTS*

4. *EVALUATION FACTORS FOR AWARD* (SECTION M)

5. *PACKAGING AND DELIVERY OF PROPOSALS*

6. *PROPOSAL INTENT RESPONSE SHEET*

7. *SAMPLE CONTRACT FORMAT* (SECTIONS B - H)

8. *CONTRACT CLAUSES - GENERAL* (SECTION I)

   General Clauses:

   This contains a listing of all General Clause Listings available. Any contract resulting from this RFP will contain the General Clause listing applicable to type of contract written and the successful offeror's organizational structure.

   Additional Contract Clauses - Specific to this RFP:

9. *LIST OF ATTACHMENTS* (SECTION J)

10. *REPRESENTATIONS AND CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS OR QUOTERS (NEGOTIATED) [WordPerfect version]* (SECTION K)

    If you intend to submit a proposal, you MUST complete this document and submit it as part of your Business Proposal. If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

11. *INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS - GENERAL* (SECTION L)

    Instructions, Conditions and Notices to Offerors - Specific to this RFP

SAMPLE CONTRACT FORMAT

Updated through FAC 2001-10
Last updated: 12/23/2002

The contract schedule set forth in SECTIONS B through H, below, is NOT an exact representation of the contract that will result from this RFP. Rather, it is a sample that provides general information pertinent to many of the contracts awarded and should be reviewed as such. Specific contractual provisions pertinent to the offeror's organizational structure (e.g. Non-Profit, Commercial, Educational) and specific cost authorizations unique to the offeror's proposal will be discussed in the negotiation process and included in the resultant contract. This sample contract is meant to provide the offeror with an overview of the elements of a typical contract.

PART I - THE SCHEDULE

PART II - CONTRACT CLAUSES

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - Representations, Certifications and Other Statements of Offerors

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The resultant contract will include a brief description of the work to be performed.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer for: 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article IF the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATION/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

The Statement of Work will either be inserted here, or referenced as an Attachment to the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Progress Reports

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports are set forth in the ***REPORTING REQUIREMENTS*** Section of the specific RFP.

b. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

c. Other Reports/Deliverables

The resultant contract will specify any additional reports required. The following are examples of the type of reports that may be required:

Note to Offeror: The following report will be required when the contract involves Human Subjects unless it has been determined by the Government that the inclusion of women and minority groups in the study population is not appropriate.

1. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of this contract. The contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. The contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES of this contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies.

If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

Note to Offeror: The following report will be required in contracts which contain one of the following Patent Rights Clauses: 52.227-11, Patent Rights-Retention by the Contractor (Short Form); 52.227-11, Patent Rights-Retention by the Contractor (Deviation); or 52.227-13, Patent Rights-Acquisition by the Government. You may wish to check the appropriate General Clause Listing to verify applicability.

2. Invention Reporting Requirement

All reports and documentation required by *[Appropriate FAR CLAUSE will be inserted]* including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of the annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer at the address listed below. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the Contracting Officer, whose address will be identified in the resultant contract.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND

SHIPPING

The resultant contract will insert specific requirements, if any, for packaging, marking, and shipping of deliverables here. If specific requirements exist, they will be described in the ***BACKGROUND/STATEMENT OF WORK*** Section of the specific RFP. Otherwise, this section will require that the Contractor guarantee that all required materials be delivered in immediate, usable, and acceptable condition.

SECTION E - INSPECTION AND ACCEPTANCE

The Contracting Officer or the duly authorized representative will inspect and accept materials and services to be delivered under the contract. The contract will identify who will perform inspections, where the inspections will be performed, and the time frame for acceptance. In addition, at least one of the following clauses will be incorporated by reference:

FAR Clause 52.246-1, CONTRACTOR INSPECTION REQUIREMENTS (APRIL 1984).

FAR Clause 52.246-2, INSPECTION OF SUPPLIES - FIXED PRICE (AUGUST 1996).

FAR Clause 52.246-3, INSPECTION OF SUPPLIES - COST-REIMBURSEMENT (MAY 2001).

FAR Clause 52.246-4, INSPECTION OF SERVICES - FIXED PRICE (AUGUST 1996).

FAR Clause 52.246-5, INSPECTION OF SERVICES-COST REIMBURSEMENT (APRIL 1984).

FAR Clause 52.246-7, INSPECTION OF RESEARCH AND DEVELOPMENT - FIXED PRICE (AUGUST 1996).

FAR Clause 52.246-8, INSPECTION OF RESEARCH AND DEVELOPMENT - COST REIMBURSEMENT (MAY 2001).

FAR Clause 52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) (APRIL 1984).

FAR Clause 52.246-16, RESPONSIBILITY FOR SUPPLIES (APRIL 1984).

If additional inspection and acceptance requirements exist, they will be described in the ***BACKGROUND/STATEMENT OF WORK*** Section of the specific RFP.

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

Note to Offeror: An Article containing the following information will be included when a COMPLETION TYPE Contract will be awarded.

Satisfactory performance of the contract shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the deliverables set forth in the ***REPORTING REQUIREMENTS*** section of the specific RFP.

The items specified for delivery will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), in accordance with the schedule to be negotiated and specified in the resultant contract and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract.

OR

ARTICLE F.1. PERIOD OF PERFORMANCE

Note to Offeror: An Article containing the following information will be included when a LEVEL OF EFFORT TYPE Contract will be awarded.

The period of performance of this contract shall be specified in the contract. Additionally, the period of performance for any option periods negotiated and anticipated will also be specified in this Article.

ARTICLE F.2. LEVEL OF EFFORT

The level of effort agreed upon in negotiations will be specified in the contract. The contract will also specify the criterion for determining satisfactory performance of this requirement.

The Government's estimated Level of Effort for this RFP is set forth in the ***INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS - Specific to this RFP (SECTION L.I)*** Section of the specific RFP.

ARTICLE F. . CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (February 1998)

The contract awarded from this RFP will incorporate the first clause listed below by reference, with the same force and effect as if it were given in full text and may incorporate, as applicable and agreed upon at negotiations one or more of the additional clauses. Upon request, the Contracting Officer will make the full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

Note to Offeror: "ALTERNATE I (APRIL 1984)," above, will be removed in Fixed-Price contracts.

52.242-17, Government Delay of Work (APRIL 1984).

52.211-11, Liquidated Damages--Supplies, Services or Research and Development (APRIL 1984).

"(a) If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, or any extension, the Contractor shall, in place of actual damages, pay to the Government as fixed, agreed, and liquidated damages, for each calendar day of delay the sum of $*[amount to be determined during negotiations]*."

52.247-35, F.O.B. Destination, Within Consignees Premises (APRIL 1984).

Note to Offeror: The above clause will be included here if the resultant contract will not contain a delivery article, i.e. Level of Effort Contract.

SECTION G - CONTRACT ADMINISTRATIVE DATA

ARTICLE G.1. PROJECT OFFICER

The Government's Project Officer(s) will be identified in the contract

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

Contractor personnel considered by the Government to be essential to contract performance will be identified here. The Contracting Officer must be notified prior to removing any of these individuals from the contract.

ARTICLE G. . WORK ASSIGNMENT PROCEDURES

Note to Offeror: The contract will contain this article if the *BACKGROUND/STATEMENT OF WORK* Section of the specific RFP indicates that the contract will use work assignments

In providing support under this contract, the Contractor shall initiate work only when so directed by a Work Assignment (Attachment provided in Section J.). Approval of a Work Assignment shall not constitute approval to exceed any item listed in the contract or general clauses of the contract. Work Assignment amounts shall not exceed the total amounts listed in the contract (time, dollars, effort, consultants, travel, etc.). The Project Officer with Contracting Officer approval, is authorized to initiate Work Assignments and to sign Work Assignments indicating satisfactory performance/delivery of the services/product required in each Work Assignment. The Contractor shall assure, prior to commencing work on any Work Assignment, that written approval of the Project Officer and the Contracting Officer has been obtained. A Work Assignment which does not contain both Contracting Officer and Project Officer approval signatures shall be considered invalid and costs incurred for such work shall be considered unallowable. The Contractor shall not exceed the estimated labor hours, estimated Work Assignment amount, or change the Work Assignment leader without prior written approval of the Project Officer and the Contracting Officer by modification of the Work Assignment. The day-to-day operational and administrative details of the Work Assignment system will be established by the Project Officer with input from the Contractor. The Work Assignment system will operate within the following general guidelines:

a. Work Assignment (W.A.) Information

(1) All work to be assigned under this contract shall relate directly to one or more of the task areas listed in the statement of work.

(2) Each W.A. shall be written for the conduct of a specific, finite task.

(3) Each new W.A. shall be numbered serially beginning with 01.

(4) Each W.A. shall be completed on the form entitled "NCI Contract Work Assignment" and listed as an Attachment in Section J of this contract.

(5) Upon award of the contract, an Administrative Work Assignment, as shown in SECTION J, Attachments, shall be issued on a yearly basis. This Work Assignment will cover the time and expenditures necessary for the administration of the contract.

b. Initiation of a W.A.

(l) The Project Officer will initiate Part I of the W.A.

(2) The Contractor shall complete Part II and obtain the appropriate signature. The Contractor shall forward the proposed W.A. to the Project Officer.

(3) Upon receipt of the proposed W.A. and after determining that the proposed W.A. is acceptable, the Project Officer will sign Part II to indicate recommendation for approval and forward to the Contracting Officer.

(4) Upon receipt, the Contracting Officer will review the proposed W.A.

(a) If approved, the Contracting Officer will sign Part II to indicate approval and will forward the W.A. to the Contractor with a copy to the Project Officer.

(b) If not approved, the Contracting Officer will notify the Project Officer, stating the reasons for disapproval.

(5) After receipt of the approved W.A., the Contractor shall begin work. The period of performance shall never precede the Contracting Officer Approval date.

c. Modification to a W.A.

(1) Each amendment to an existing work assignment shall contain the original W.A. number and shall designate a modification number. Modification numbers for each W.A. shall be serially numbered beginning with 01 (for example, Work Assignment 01, Modification No. 01).

(2) Each W.A. modification shall set forth in specific detail which portion(s) of the W.A. is to be modified. All Cost/Labor modifications shall be in the following format:

	Authorized to Date	This Modification	Revised Estimate
Labor Hours			
Cost Elements (List Each Element)			

d. Conclusion of a W.A.

(1) For each W.A. performed, the Contractor shall prepare PART III of the W.A. for submission to the Contracting Officer.

(2) This PART III submission shall include all actual information (cost, effort, and deliverables) relative to the W.A.

(3) PART III of the W.A. shall be submitted as soon as possible and not to exceed three months after the closing date of the W.A. For those Work Assignments which expire within three months prior to the contract expiration date, PART III of the Work Assignment shall be submitted on the final contract day.

(4) After verification that all work is complete and deliverables have been received and accepted, the Project Officer will sign Part III of the W.A. to indicate recommendation for approval and forward the W.A. to the Contracting Officer.

(5) After verification that the W.A. has been satisfactorily completed, the Contracting Officer will approve completion of the W.A. by signing Part III of the W.A. and forward to the Contractor.

ARTICLE G. . METHOD OF ORDERING

Note to Offeror: These Articles will be included in INDEFINITE DELIVERY Type Contracts.

The Consignees/Ordering Officials shall sign all orders (including written confirmation of oral/telephonic orders) involving requests for supplies and/or services under this contract. Each delivery shall be accompanied by a packing slip or other evidence of delivery/performance.

The authorized designees will be designated in the contract.

The contractor representative(s) authorized to receive and accept orders placed by telephone will be designated in the contract,

ARTICLE G. . INDEFINITE DELIVERY CONTRACT PAYMENT METHOD

To initiate and receive prompt payment, the Contractor shall comply with the following procedure:

a. A Record of Call Number or Task/Delivery Order Number shall be given to you at the time the

order is placed. The Contractor is cautioned not to accept an order unless one of these Numbers is issued.

b. Invoices shall be submitted monthly to the address indicated in ARTICLE G. . INVOICE INSTRUCTIONS of this contract. Invoices shall cite the Contract Number and the Record of Call Number or Task/Delivery Order Number for each order for which payment is being requested. See ARTICLE G. . INVOICE INSTRUCTIONS for more information about submission of a proper invoice.

To record and receive the Record of Call, the Consignees/Ordering Officials as designated in ARTICLE G. . METHOD OF ORDERING, shall comply with the following procedure.

The Record of Call shall be entered into the Delegated Procurement System (DELPRO) at the time the order is placed. As deliveries are made, the receiving information shall be entered into the DELPRO system.

ARTICLE G. . RECIPIENTS REIMBURSEMENT PROCEDURES

Note to Offeror: The contract will contain this article if the *BACKGROUND/STATEMENT OF WORK* Section of the specific RFP indicates that the contract will generate income.

a. During the course of this contract, the Contracting Officer or his duly designated representative will notify the Contractor to make certain shipments of *[type of material will be specified in the contract]* directly to specified U.S. Government Recipients; Contractor/Government Agencies/or other private organizations and the Contractor shall make such shipments as directed.

b. The Contractor shall bill recipients directly for the *[type of material will be specified in the contract]* provided. The charges for these *[type of material will be specified in the contract]* shall be based upon the current National Cancer Institute price list for the items listed in an Attachment in Section J of this contract. Under no circumstances shall the Contractor bill prices other than those listed in the referenced price list. Prices listed are subject to change. Revised price lists will be issued by the Government when appropriate without the concurrence of the Contractor.

c. The Contractor shall keep an accurate account of all payments received from recipients of *[type of material will be specified in the contract]* separate from other fiscal aspects of the contract. The Contractor shall record as credits on monthly vouchers to the Government, all payments received from the Government Grantees, Contractors, Government Agencies, or other private organizations. The income from recipients must be credited to the Government in the billing period actually received. Thus, the Contractor shall bill the Government directly for payment of contract costs and shall subtract as a credit all payments received from recipients. The actual

collections from sales will be offset against the gross billing leaving a net amount due on the invoice.

The National Cancer Institute Project Officer may direct from time to time that shipments be made entirely at Government expense.

d. The Contractor shall account for the contract related income separately in accordance with its own double entry accounting system. The Contractor shall submit to the Government a Monthly Summary Sheet of Sales which is listed as an Attachment in Section J of this contract. The Contractor shall submit a copy of this Attachment each month with the Monthly Progress Report.

The administration of the contract related income shall be subject to the terms of this contract, including specifically and without limitation, the Audit--Negotiation Clause (FAR 52.215-2) of the General Clauses, and the applicable cost principles of the Federal Acquisition Regulation. e. The Contractor shall use the following procedures for collection of delinquent accounts:

Step 1 - Accounts 30 days past due. A copy of the invoice shall be sent to the recipient with a notation that the account is overdue and request payment.

Step 2 - Accounts 60 days past due. The Contractor shall turn the account over to a collection agency.

f. When the completion (final) invoice is submitted on this contract, a listing of all outstanding recipient invoices shall be provided along with details as to what disposition is expected on each.

ARTICLE G. . INVOICE SUBMISSION

Invoices will be submitted in accordance with the Invoice/Financing Request Instructions Forms specificed in the ***LIST OF ATTACHMENTS (SECTION J)*** of the specific RFP.

For cost-type contracts that will require a separate submission of a separate Contract Financial Report, NIH(RC)-1, “Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts” will be used.

For cost-type contracts that will require the financial information submitted along with the invoice, NIH(RC)-4, “Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts” will be used.

For fixed-price contracts, NIH(RC)-2, “Invoice Instruction for NIH Fixed-Price Type Contracts”

will be used.

For offerors who are under Letter of Credit, payments will be provided in accordance with Alternate V-Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments, which will be included in full text in any resultant contract.

Addresses for submitting invoices will be included in the contract.

ARTICLE G. . CONTRACT FINANCIAL REPORT

Financial reports will be submitted using the Form NIH 2706, "Financial Report of Individual Project/Contract." If applicable, the NIH 2706, and the Instructions which accompany the form, will be included in the ***LIST OF ATTACHMENTS (SECTION J)*** of the specific RFP.

Normally, reports are due quarterly. Examples of the cost elements to be reported include:

(1) Direct Labor
    (a) Principal Investigator
    (b) Co-Principal Investigator
    (c) Key Personnel
(2) Personnel - Other
(3) Fringe Benefits
(4) Materials/Supplies
(5) Patient Care Costs
(6) Travel
(7) Consultant Costs
(8) Subcontract Costs
(9) Other Direct Costs
(10) Indirect Costs
(11) Total Cost
(12) Fee
(13) Total Cost Plus Fixed Fee

ARTICLE G. . INDIRECT COSTS

Profit making organizations will negotiate provisional and/or final indirect cost rates with:

Director, Division of Financial Advisory Services
Office of Acquisiton Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

ARTICLE G. . GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, Contractor's Guide for Control of Government Property, (1990).

ARTICLE G. . POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreements cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address: http://ocm.od.nih.gov/cdmp/cps_contractor.htm

The registration process requires the contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The following Articles may not apply to every contract. If you have any questions about the applicability and the affect that any Article may have on your proposal, contact the Contracting Officer Identified on the SOLICITATION/CONTRACT FORM COVER PAGE of the specific RFP.

ARTICLE H. . REIMBURSEMENT OF COSTS FOR INDEPENDENT RESEARCH AND DEVELOPMENT PROJECTS (Commercials Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized procedures for stimulating and supporting this independent research by selecting from multitudes of applications those research projects most worthy of support within the constraints of its appropriations. The reimbursement through the indirect cost mechanism of independent research and development costs not incidental to product improvement would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all organizations may compete for direct funding of independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health

Service grant office for review. Since these projects may be submitted for direct funding, the Contractor agrees that no costs for any independent research and development project, including all applicable indirect costs, will be claimed under this contract.

ARTICLE H. . HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

ARTICLE H. . HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by *[to be inserted in the contract]*, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed Optional Form 310 certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the Optional Form 310.

ARTICLE H. . REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the

protection of human subjects that has been coompleted for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H. . DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring [BOARD and PLAN] shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H. . HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H. . HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed Optional Form 310 certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the Optional Form 310.

ARTICLE H. . CONTINUED BAN OF FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. Public Law and Section No. Fiscal Year Period Covered

[applicable information to be included at award]

ARTICLE H. . NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. Public Law and Section No. Fiscal Year Period Covered

[applicable information to be included at award]

ARTICLE H. . PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

The Privacy Act System of Records applicable to this project is Number *[to be included in contract]*. This document is incorporated into this contract as an Attachment in SECTION J of the contract.

ARTICLE H. . EVALUATION PROJECTS

All publications including reports, compilations of data, articles and the like resulting from this contract shall contain the statement below. It shall be located on the cover, inside cover, or title page.

This project *[NIH EVALUATION PROJECT NUMBER AND CONTRACT NUMBER will be inserted]* received support from the evaluation set-aside Section 513, Public Health Service Act.

ARTICLE H. . ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at http://grants1.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H. . INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NCI environment (NIH) directly, or through collaborative research or holding facilities under contract to NCI except by permit. Direct shipments to NIH from an approved commercial vendor will be considered exempt. Non-exempt sources must be approved by permit issued through the National Center for Research Resources (NCRR). The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, NCI environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted not less than 30 days prior to shipping date to: NIH Veterinary Resources Program (VRP), National Center for Research Resources (NCRR), Scientific Services Branch, Laboratory Sciences Section, Building 28A, Room 106, 28 LIBRARY DR MSC 5210, BETHESDA MD 20892-5210, (301)496-2527.

ARTICLE H. . OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H. . OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of (the base period, Phase I, or Year I) set forth in the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-***** set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform (Phases(s) or Year(s)) of the Statement of Work as also defined in Sections C and F of this contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in Article B.

**Clause number will be determined during negotiations.*

Note to Offeror: If Options are applicable, the specific RFP shall identify all necessary information about options including requirements for proposal preparation, if any, and the evaluation of options.

ARTICLE H. . SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated is attached hereto and made a part of this contract.

(2) The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

(1) **Subcontracting Report for Individual Contracts, SF-294**

The Contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

April 30th
October 30th

The Report shall be sent to the following address:

Contracting Officer
Research Contracts Branch
National Cancer Institute, NIH
EPS, Room
6120 EXECUTIVE BLVD MSC
BETHESDA MD 20892-

(2) **Summary Subcontract Report, SF-295**

The Contractor shall submit two (2) copies of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. The Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

The first Report shall be submitted after the first full year of this contract in addition to any fractional part of the year in which this contract became effective.

One copy of this report shall be sent to the Contracting Officer at the address above. One copy of this Report shall be mailed to the Office of Small and Disadvantaged Business Utilization, DHHS at following address:

Office of Small and Disadvantaged Business Utilization
Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 517-D
200 Independence Avenue, S.W.
Washington, D.C. 20201

(3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 606-4000, X234 for the correct address if unknown.

ARTICLE H. . SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to Public Law(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of applicable amount shown for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead, and general and administrative expenses (also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an infividual may be permitted to earn outside of duties to the contractor. The per year salary rate limit also applies to individuals proposed under subcontracts. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate exceeds any salary rate ceiling established in future DHHS appropriation acts.

b.	Public Law and Section No.	Fiscal Year	Dollar Amount of Salary Limitation*

[applicable information to be included at award] *

Currently this amount is $*[to be inserted in contract]* and will remain at this level until such time as the Executive Level I is increased. See the following web site for Executive Schedule rates of pay:

LINK TO EXECUTIVE LEVEL SALARIES: http://www.opm.gov/oca/PAYRATES/index.htm
(Click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years.)

ARTICLE H. . INFORMATION TECHNOLOGY SYSTEMS SECURITY SPECIFICATIONS

The Contractor agrees to comply with the Information Technology system security and/or privacy specifications set forth in the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The Contractor further agrees to include this provision in any subcontract awarded pursuant to this prime contract. NOTE: OMB A-130 is accessible via web site: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt

DHHS Automated Information Systems Security Program Handbook is accessible via web site: http://irm.cit.nih.gov/policy/aissp.html

ARTICLE H. . ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/

The standards applicable to this requirement are *[identified in the **BACKGROUND/STATEMENT OF WORK** Section of the specific RFP]*:

ARTICLE H. . ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see http://www.energystar.gov/
For more information about FEMP see http://www.eren.doe.gov/femp/procurement

ARTICLE H. . CONFIDENTIALTIY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (APRIL 1984):

[The specific information applicable to this clause will be included in the contract]

ARTICLE H. . PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services under Contract No. *[contract number will be inserted]*.

ARTICLE H. . PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. Public Law and Section No. Fiscal Year Period Covered

[applicable information to be included at award]

ARTICLE H. . TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with FAR 16.505(b)(5), the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

[To be included in contract]

ARTICLE H. . REPORTING MATTERS INVOLVING FRAUD, WASTE, AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477**). All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H. . YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

2. Noncommercial Supply Items Warranty

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

The contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the item documentation provided by the contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

LIST YEAR 2000 COMPLIANT ITEMS:

(end of clause)

3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The contractor warrants that each hardware, software and firmware product delivered under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the product documentation provided by the contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

LIST YEAR 2000 COMPLIANT ITEMS:

(end of clause)

ARTICLE H. . ANTI-LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall not be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. Public Law and Section No. Fiscal Year Period Covered

[applicable information to be included at award]

ARTICLE H. . LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established by section 202 of the Controlled Substances Act (21 U.S.C. 812). This limitation shall not apply when the contractor makes known to the contracting officer that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

b. Public Law and Section No. Fiscal Year Period Covered

[applicable information to be included at award]

The following Article will be included in all Research & Development Contracts.

ARTICLE H. . OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : http://ott.od.nih.gov/NewPages/64FR72090.pdf. is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools," "research materials," and "research resources" are used interchangeably and have the same meaning.

The following Article will be included in all contracts in which the possibility of a federally funded, in whole or in part, meeting, convention, conference or training seminar exists.

ARTICLE H. . HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines a described in the Public Law. This restriction applies to public accommodations both foreign an domestic.

Public accommodations that meet the requirements can be accessed at:
http://www.usfa.fema.gov/hotel/index.htm